REMARKS/ARGUMENTS

Claims 1-74 have been presented in this case. Claims 48, 51-53, 58, 60, 61, 64-67, 72, and 74 are currently pending.

Claims 1-47 were cancelled.

Claim 48 is currently amended.

Claims 49 and 50 are canceled.

Claim 51 is currently amended.

Claim 52 is unchanged from the immediate prior version.

Claim 53 is currently amended.

Claims 54 and 55 were cancelled.

Claims 56 and 57 are cancelled.

Claim 58 is unchanged from the immediate prior version.

Claim 59 is canceled.

Claims 60 and 61 are currently amended.

Claims 62 and 63 are canceled.

Claim 64 is currently amended.

Claims 65 and 66 are unchanged from the immediate prior version.

Claim 67 is currently amended.

Claims 68-71 are canceled.

Claim 72 is currently amended.

Claim 73 is canceled.

Claim 74 is currently amended.

The term "active principle" has been replaced by "active substance" in order to make the claims language more clear in claims 48, 51, 53, 61, 64, and 67.

Claims 48 and 61 have been amended to specify the amount and nature of each component of the tablet.

Claim 48 has been amended to describe the nature of the component as the applicant mentioned in canceled claims 49, 50, 55 and 59. Claim 61 has been amended to describe the nature of the component as the applicant mentioned in canceled claims 62, 63, 68, 69 and 73.

CLAIM REJECTIONS UNDER 35 USC § 112

In the December 30, 2004 Office Action, the Examiner rejected claim 69 for failure to meet the requirements of 35 U.S.C. §112. The applicant has canceled claim 69, thus the rejection is now moot.

CLAIM REJECTION UNDER 35 USC § 103 (a) as being unpatentable over Ohno et al. (US 5,958,453) in view of Gowan (US 5,876,759)

Ohno et al. teach a solid pharmaceutical composition with improved disintegrability which contains a mixture of active principles, which are not coated, erythritol, mannitol, crystalline cellulose, crospovidone, magnesium stearate and light anhydrous silic acid.

Regarding the polyol, the use of mannitol as filler is disclosed however, it is not a directly compressible mannitol.

Anhydrous silic acid is disclosed, however, this is not one of the permeabilizing agent according to claim 48.

The inclusion of a permeabilizing agent according to the invention is thus not taught by Ohno et al.

Gowan, describes rapidly disintegrating tablet containing coated active substance, mannitol, microcrystalline cellulose, aspartame, 0.06% of colloidal silicon dioxide and stearic acid.

Gowan is thus silent on the use of crospovidone or croscarmellose, which are superdisintegrants which are essential constituents of the tablets according to the invention. The examiner seems to indicate that colloidal silicon dioxide is a permeabilizing agent according to the invention.

Permeabilizing agents according to the invention are specifically recited in claim 48 (and claim 61), however, colloidal silicon dioxide is not mentioned.

Furthermore, the amount of colloidal silicon dioxide is too low in order to fulfill the function of the permeabilizing agent according to the invention.

In fact, according to the invention, the function of the permeabilizing agent is to create a hydrophilic network, thus assisting the fast-disintegration of the tablet and moreover, allowing the reduction of the amount of lubricants needed to ensure optimum manufacturing conditions, and the reduction of the intensity of the compression needed to produce a tablet, said reduction of the compression strength being an important feature not to impair the coating of the active substance.

The applicant thus respectfully submits that the pending claims are NOT obvious over Ohno in view of Gowan as the Examiner stated in the December 30, 2004 Office Action. Additionally, even if the one skilled in the art would have been motivated to combine the two teachings he would never have obtained the tablet according to the

invention particularly since the specific nature and amount of permeabilizing agent is disclosed neither in Gowan nor in Ohno.

Thus, the combination of these two prior art, does not lead to the multiparticulate tablet of the instant invention.

Claims 48 and 61 are thus NOT obvious in view of Ohno et al in combination with Gowan. In that claims 51-53, 58, 60 are dependant on claim 48 and claims 62-67, 71, 72 and 74 are dependant on claim 61, they are likewise not obvious.

NON STATUTORY DOUBLE PATENTING REJECTION

It is respectfully submitted that, in the instant application, a permeabilizing agent is needed and is an essential feature of the tablet, as set forth in amended claim 48 above. The Applicant specifies the nature of the permeabilizing agent by amending claim 48, in order to make clear that the required permeabilizing agents are selected from the group consisting of hydrophilic precipitated silica maltodextrins, β-cyclodextrines and mixtures thereof.

The permeabilizing agent of the instant invention is of particular importance, since it favors the rearrangements of particles during compression and allows using a reduced intensity of compression, leading to a tablet with improved palatability and further create a hydrophilic network, thus assisting the fast-disintegration of the tablet.

This feature does not exist in claim 1 of US 6,106,861 and one skilled in the art could not deduce from any claim of US 6,106,861 that this ingredient was of particular importance.

Hence, the instant application includes a technical feature which was not claimed in US 6,106,861 and was not obvious from this patent either.

It is respectfully submitted that the presence of this new technical feature makes the instant patent application a patentably distinct invention from US 6,106,861.

The Examiner stated that he felt that it would have been obvious to one of ordinary skill in the art to utilize a silica in the composition of US 6,106,861 since Ku et al. teaches the advantages of using an anti-adherent agent in reducing the stickiness of the composition to metal surfaces during the process of making the dosage forms.

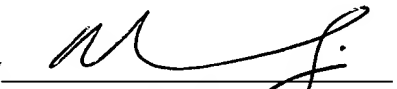
Applicants respectfully disagree since, on the one hand, there is no incentive to combine US 6,106,861 with Kiu et al, because Kiu et al. does not relate to tablet to be disintegrated in the oral cavity, and on the other hand, there is no indication that the dioxide silicon of Kiu et al. will act as the permeabilizing agent of the invention in forming an hydrophilic network which enhances the disintegration of the tablet. Consequently, Applicants submit that the double patenting rejection of claims should be withdrawn.

In view of the above remarks, Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If there are any remaining issues which can be expedited by a telephone conference, the examiner is courteously invited to telephone the counsel at the number indicated below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

April 12, 2004

By 
Kevin A. Keeling
Registration No. 51,867
Customer No. 03000
(215) 567-2010
Attorneys for Applicants

Please charge or credit our Account No. 03-0075 as necessary to affect entry and/or ensure consideration of this submission.